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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,021	11/26/2003	Keith M. Orr	22956-239	7261
21125 7590 03/02/2010 NUTTER MCCLENNEN & FISH LLP SEAPORT WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604				
EXAMINER				
DÖRNBUSCH, DIANNE				
ART UNIT		PAPER NUMBER		
3773				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doctet@nutter.com

Office Action Summary

Application No.

10/724,021

Applicant(s)

ORR ET AL.

Examiner

DIANNE DORNBUSCH

Art Unit

3773

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-13, 15-18, 20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-13 and 15-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/888)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

1. The Advisory Action submitted on November 9, 2009 has been vacated.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claim 1 recites the limitation "the flared proximal end" in line five. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Evans et al. (2004/0204715).

Evans discloses the following claimed limitations:

Claim 1: A first component (300) for receiving and dispensing the tissue scaffold having a funnel-shaped proximal end (320), a distal end (330), and an elongate, hollow body (310) extending therebetween (Fig. 2), the elongate body defining a passageway extending from the flared proximal end to the distal end (Fig. 5); and a second component (100) having an elongate body (110) with a tip at a distal end (Fig. 2 and 5), the elongate body being configured to be removably disposed within the first component for sliding along the passageway (Fig. 1-2), the second component including at least one sealing ring (150) around the elongate body proximal to the tip (Fig. 2 and 5).

Regarding the statement that the first component is for receiving and dispensing the tissue scaffold and that the second component slides along the passageway, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Claim 2: Wherein the passageway includes a first, flared portion extending into a second, tubular portion (Fig. 5).

Claim 3: Wherein the first, flared portion has a curved tapered shape (Fig. 2 and 5)

Claim 4: Wherein the flared proximal end of the first component has a diameter in the range of about 15 mm to about 50 mm ([0048]).

Art Unit: 3773

Claim 5: Wherein the second, tubular portion has a diameter in the range of about 5 mm to about 17 mm ([0042]).

Claim 6: Wherein the tip of the second component comprises a spherical tip (Fig. 5)

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 7, 9-13, and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. (2004/0204715).

Claim 7: Evans teaches all the claimed limitations discussed above however, Evans does not disclose that the spherical tip has a diameter in the range of about 6 mm to about 10 mm.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Evans with the diameter range since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Furthermore, the differences in concentration, temperature, size, or pressure will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration, temperature, size, or pressure is critical.

"[W]here the general conditions of a claim are disclosed in the prior art, it is not

inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP 2144.05 (II). Claim 9: Evans discloses an insertion tube (300) having a funnel-shaped proximal end (320), a distal end (330) and a hollow passageway extending therebetween (Fig. 5); and an insertion rod (100) having an elongate shaft (110) extending into a handle (120) at a proximal end (Fig. 2) and a blunt tip at a distal end (Fig. 2 and 5), the elongate shaft being configured to be removably disposed within the insertion tube for sliding along the passageway (Fig. 1-2) and contacting the tissue scaffold disposed within the insertion device (the tip contact the material inside the passageway as it is being pushed out of the insertion tube); the insertion rod including a sealing ring (150) around the elongate shaft (Fig. 2 and 5).

Regarding the use of a scaffold and that the second component slides along the passageway, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Evans teaches all the claimed limitations discussed above however, Evans does not disclose that the insertion rod further includes a pair of sealing rings around the elongate body.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have a second sealing ring since the examiner is taking Official Notice that the use of a second sealing ring is well known in the art in order to

control the sliding resistance between the first components and the second component as well as providing a seal.

Claim 10: Evans discloses that the passageway includes a first, flared portion extending into a second, tubular portion (Fig. 2 and 5).

Claim 11: Evans discloses that the first, flared portion has a curved, tapered shape (Fig. 2 and 5).

Claim 12: Evans discloses that the second, tubular portion has a diameter in the range of about 6 mm to about 17 mm ([0048]).

Claim 13: Evans discloses all the claimed limitations discussed above except the second, tubular portion has a diameter in the range of about 7 mm to about 9 mm. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Evans with the diameter range since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claim 15: Evans discloses that the flared proximal end of the insertion tube has a diameter in the range of about 15 mm to about 50 mm ([0048]).

Claim 16: Evans discloses that the blunt tip of the insertion rod comprises a spherical tip (Fig. 2 and 5).

Claims 17 and 18: Evans teaches all the claimed limitations discussed above however, Evans does not disclose that the spherical tip has a diameter in the range of about 6 mm to about 10 mm.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Evans with the diameter range since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Furthermore, the differences in concentration, temperature, size, or pressure will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration, temperature, size, or pressure is critical.

"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP 2144.05 (II).

Response to Arguments

9. Applicant's arguments filed October 27, 2009 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The patents Ritcher et al. (4,232,670) and Thornhill et al. (6,019,765), all disclose a funnel at the proximal end of a syringe.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

Art Unit: 3773

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./
Examiner, Art Unit 3773

/Julian W. Wool/
Primary Examiner, Art Unit 3773